

RESPONSE

Claims 14-39 were pending in the Application. Claims 14-25, 27, and 28 are amended, and new claim 40 is added. Upon entry of the present Amendment, claims 14-40 will be pending and presented for reconsideration. Applicant respectfully submits that no new matter is introduced by the present Amendment. A marked-up copy of the amended claims, and a clean copy of all pending claims, are attached.

Support for amendment to claim 14 can be found in the Specification at, for example, page 3, lines 2-6 and page 9, lines 15-20. Claims 15-25 and 28 are amended to correct formal matters in view of the amendment to claim 14. Support for amendment to claim 27 can be found in the Specification at, for example, page 10, lines 6-20. Support for the new claim 40 can be found in the Specification at, for example, page 9, lines 21-27.

Rejections Under 35 U.S.C. § 102

Claims 14 and 22-25 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,053,033 to Clarke ("Clarke").

Claims 22-25 depend from claim 14, which is amended to recite a method of ablating mucosal or endothelial lining. Steps recited in the amended claim 14 include ablating the mucosal or endothelial lining with high intensity ultraviolet light generated by a flash lamp, while avoiding causing substantial damage to the muscle layer underneath the lining.

Clarke describes systems and methods aimed at preventing restenosis after angioplasty (col. 1, lns. 6-10). Clarke's methods are based on the belief that killing smooth muscle cells at an angioplasty site would reduce the risk of restenosis (col. 2, lns. 39-50). Clarke's various embodiments are designed to lesson obstruction at an angioplasty site by substantially reducing the amount of smooth muscle cells at the site (col. 5, lns. 6-9 and lns. 52-62). In contrast to the method recited in the amended claim 14, methods described in Clarke do not "damag[e] either the *inner endothelium layer* 22 or the outer adventitia 26 of the blood vessel" (col. 5, lns. 1-5) (emphasis added). As shown in FIGS. 3B, 3C, 6B, and 6C of the Clarke patent, various embodiments described in Clarke use radiation aimed at smooth muscle cells 40, the number of which appears substantially reduced after the treatment. In these same figures, the endothelial layer 22, however, appears unaffected by the treatment.

Accordingly, Clarke does not teach ablating mucosal or endothelial lining as expressly recited in amended claim 14. Nor does Clarke teach avoiding substantial damage to the muscle layer underneath the lining, also expressly recited in amended claim 14. Accordingly, Applicant respectfully requests that the rejections of claim 14 and its dependent claims under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 14-21 and 25-39 were each rejected under 35 U.S.C. § 103(a) as being obvious over Clarke in combination of one of the following references: U.S. Patent Nos. 5,405,369 to Selman *et al.* ("Selman"), 5,814,041 to Anderson *et al.* ("Anderson"), 5,207,672 to Roth *et al.* ("Roth"), and 4,799,479 to Spears ("Spears").

Selman describes photodynamic treatment of gastro-intestinal tissue transplanted in a recipient organ such as the bladder. More specifically, the method described in Selman destroys the mucosal layer of the transplanted tissue while sparing the submucosal and muscular layers (col. 3, lns. 46-59). As the Examiner recognizes, Selman does not teach the use of a flash lamp, as recited in the instant claim 14.

In fact, both Clarke and Selman teach away from their combination. Both references are very specific about the layer to be destroyed to achieve respectively desired effects, and the two references target mutually exclusive layers. In Clarke, the smooth muscle layer is destroyed while the mucosal layer is saved. Conversely, in Selman, it is the mucosal layer that is destroyed while the muscle layer is saved to maintain "desired elastic and strength [properties]" (col. 3, lns. 1-3). Effective optical destruction of a specific tissue layer requires light of a specific wavelength, and accordingly, requires specific light devices that generate such wavelength. For example, Clarke provides a chart (Table 1) showing that laser at wavelength of 266 nm, and not higher wavelengths, being critical in effectively destroying smooth muscle cells. Therefore, one skilled artisan would be dissuaded from combining the disclosure of Clarke and Selman.

Anderson describes using a laser-illuminator that has a differential optical radiator to ablate endometrium, the mucous membrane lining the uterus. As the Examiner recognizes, Anderson does not teach the use of a flash lamp, an element recited in the instant claim 14. Like Selman, Anderson describes a method that targets a tissue layer different from the one targeted

by Clarke. Anderson also warns that “the intensity of illumination,” which partly depends on the frequency of the light, “is correlated with the extent of photodynamic killing of target cells or tissue” (col. 5, lns. 10-15). Accordingly, one skilled artisan would also be dissuaded from combining the disclosure of Clarke and Anderson.

Roth describes inducing general necrosis of selected tissues in a constricted passageway through thermal coagulation with minimal or no ablation (col. 5, ln. 35-col. 6, ln. 6). The necrosed tissue, according to Roth, is later removed by normal body processes such as urination. Roth does not teach ablating the mucosal or endothelial lining while avoiding substantial damage to the muscle layer underneath, as recited in the amended claim 14. Nor does Roth teach the use of a flash lamp, which, as described in the instant specification, is a gaseous discharge lamp that produces light of short duration and high intensity (page 6, lns. 4-5). Therefore, the combination of Clarke and Roth would be inappropriate and insufficient as a basis for rejecting the instant claims.

Spears describes heating an expanded intraluminal balloon to fuse together fragmented segments of tissue and to coagulate blood trapped within dissected planes of tissue and within fissures created by a wall fracture (*see* Abstract). Spears does not teach ablating the mucosal or endothelial lining while avoiding substantial damage to the muscle layer underneath, as recited in the amended claim 14. Nor does Spears teach the use of a flash lamp. Therefore, the combination of Clarke and Spears would be inappropriate and insufficient as a basis for rejecting the instant claims.

In sum, combination of the references cited under this section is either inappropriate or/and insufficient to maintain a rejection of amended claim 14 and its dependent claims under 35 U.S.C. § 103. In light of the foregoing reasons and amendments to claim 14, Applicant respectfully requests that the rejections of claim 14 and its dependent claims under 35 U.S.C. § 103 be reconsidered and withdrawn.

Information Disclosure Statement

Applicant is submitting a Supplemental Information Disclosure Statement with this paper. Applicant kindly requests the Examiner to initial and return ~~ten~~ pages of the Form PTO-


1449 previously submitted in an Information Disclosure Statement dated February 8, 2002,
together with the **one** page Form PTO-1449 submitted herewith.

CONCLUSION

If the Examiner believes that a telephone conversation with Applicant's attorney would expedite allowance of this application, the Examiner is cordially invited to call the undersigned attorney at (617) 310-8108.

Respectfully submitted,

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Marked-up Version of All Claim Amendment

14. (Twice Amended) A method for ~~illuminating tissue~~ablating mucosal or endothelial lining, comprising:

- a) providing a light device comprising a flash lamp;
- b) inserting the light device inside a body near ~~tissue~~a mucosal or endothelial lining to be ~~illuminated~~ablated, the mucosal or endothelial lining being on top of a muscle layer;
- c) energizing the ~~light device~~flash lamp to generate a high intensity ultraviolet light; and
- d) ~~illuminating the tissue~~ablating the mucosal or endothelial lining by applying with the generated light to the tissue, and avoiding causing substantial damage to the muscle layer underneath.

15. (Amended) The method of claim 14 wherein the mucosal lining ~~illuminating the tissue~~comprises ablating a mucosal lining of an esophagus.

16. (Amended) The method of claim 14 wherein the mucosal lining ~~illuminating the tissue~~comprises ablating a mucosal lining of a throat.

17. (Amended) The method of claim 14 wherein the mucosal lining ~~illuminating the tissue~~comprises ablating a mucosal lining of an intestine.

18. (Amended) The method of claim 14 wherein the mucosal lining ~~illuminating the tissue~~comprises ablating a mucosal lining of a colon.

19. (Amended) The method of claim 14 wherein the endothelial lining ~~illuminating the tissue~~comprises ablating an endothelial lining of a uterus.

20. (Amended) The method of claim 14 wherein the endothelial lining ~~illuminating the tissue~~comprises ablating an endothelial lining of a urethra.

21. (Amended) The method of claim 14 wherein the endothelial lining ~~illuminating the tissue~~ comprises ablating an endothelial lining of a bladder.

22. (Amended) The method of claim 14 wherein the endothelial lining ~~illuminating the tissue~~ comprises ablating an endothelial lining of an organ.

23. (Amended) The method of claim 14 wherein the endothelial lining ~~illuminating the tissue~~ comprises ablating an endothelial lining of a duct.

24. (Amended) The method of claim 14 wherein the endothelial lining ~~illuminating the tissue~~ comprises ablating an endothelial lining of a vessel.

25. (Amended) The method of claim 14 further comprising disposing the light device at a distal end of an interventional device and inserting the interventional device inside a the body near the mucosal or endothelial lining ~~tissue~~ to be ~~illuminated~~ ablated.

27. (Amended) The method of claim 14 further comprising characterizing a targeted portion of the mucosal or endothelial lining ~~the tissue~~ by transporting a dye to the ~~tissue~~ the mucosal or endothelial lining to stain the ~~tissue~~ targeted portion and wherein the step of ablating the mucosal or endothelial lining ~~illuminating the tissue~~ comprises ablating the tissue using light absorbed by the stained ~~tissue~~ portion.

28. (Amended) The method of claim 14 further comprising introducing a drug near the mucosal or endothelial lining ~~tissue~~ and activating the drug through ~~illumination~~ the light.